BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :		(11) International Publication Number:
A61M 29/00 // A61F 2/04 A61M 25/04	A1	WO 93/13824
		(43) International Publication Date: 22 July 1993 (22.07.93)

(21) International Application Number: PCT/DK93/00015

(22) International Filing Date: 19 January 1993 (19.01.93)

(30) Priority data:
0061/92 20 January 1992 (20.01.92) DK

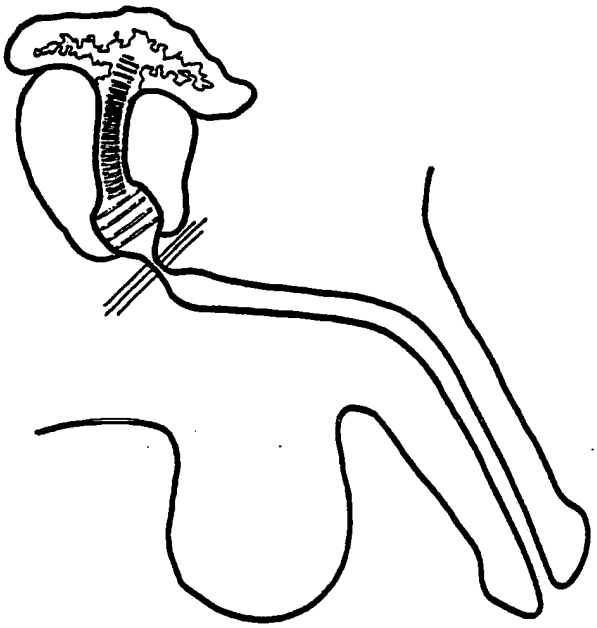
(71) Applicant *(for all designated States except US)*: ENGINEERS & DOCTORS A/S [DK/DK]; Saunte Bygade 12, DK-3100 Hornbæk (DK).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)* : OTHEL-JACOBSEN, Erik [DK/DK]; Turbinevej 7, DK-3150 Hellebæk (DK). HARBOE, Henrik [DK/DK]; Bjerggårdsvænget 17, DK-2840 Holte (DK).

(81) Designated States: AT, AU, BB, BG, BR, CA, CH, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, LK, LU, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, SN, TD, TG).

Published
With international search report.

(54) Title: SEGMENTARILY EXPANDABLE TUBULAR ENDOLUMINAL PROSTHESIS



(57) Abstract

The invention concerns a segmentarily expandable tubular endoluminal prosthesis (a stent) comprising a helically coiled, or otherwise as a tubular structure shaped, wire of Nickel-Titanium alloy with shape memory effect (SMA). In its primary shape the diameter of one or more segments of the stent is considerably greater than the rest of the diameter of the stent. In its secondary shape the segments and possibly the total stent diameter is reduced to an extent allowing insertion of the stent into a body cavity. Once in the desired position in the body cavity the stent can return to its primary shape by exposing the stent to heat.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NL	Netherlands
BE	Belgium	GN	Guinea	NO	Norway
BF	Burkina Faso	GR	Greece	NZ	New Zealand
BG	Bulgaria	HU	Hungary	PL	Poland
BJ	Benin	IE	Ireland	PT	Portugal
BR	Brazil	IT	Italy	RO	Romania
CA	Canada	JP	Japan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo			SE	Sweden
CH	Switzerland	KR	Republic of Korea	SK	Slovak Republic
CI	Côte d'Ivoire	KZ	Kazakhstan	SN	Senegal
CM	Cameroon	LI	Liechtenstein	SU	Soviet Union
CS	Czechoslovakia	LK	Sri Lanka	TD	Chad
CZ	Czech Republic	LU	Luxembourg	TG	Togo
DE	Germany	MC	Monaco	UA	Ukraine
DK	Denmark	MG	Madagascar	US	United States of America
ES	Spain	ML	Mali	VN	Viet Nam
FI	Finland	MN	Mongolia		

SEGMENTARILY EXPANDABLE TUBULAR ENDOLUMINAL PROSTHESIS

The invention concerns a tubular endoluminal prosthesis (in the following called: A "stent"), comprising a helically coiled, or otherwise as a tubular structur shaped, single wire of Nickel-Titanium alloy with shape memory properties (in the following called SMA for: Shape Memory Alloy) and a primary shape where one or more segments has a diameter considerably greater than the rest of the stent and a secondary shape where the segment or those segments with the greater diameter or perhaps the total coil is turned to the same lesser diameter. On activation of the shape memory effect of the material the stent will expand because it is tranformed from the secondary shape back to the primary shape.

The stent will keep the same length before and after expansion with a particularly desirable relation between the expansion and the space between the threads before and after expansion.

The single wire design of the stent is a particular advance when the stent is to be removed from a body cavity because the SMA becomes soft (superelastic) when it is cooled. The stent can be removed by grasping any part of it and pulling it out as a thread.

Other stents of helically coiled metal wire such as spring steel are known for placement in the part of the male urethra passing through the prostate gland. German patent number DE 28 27 908 C2 and German patent application number 25 28 273. A considerable disadvantage to the known stent is that after placement it sometimes slides away from the desired position in the urethra because the stent stays with the diameter it had at placement. Space does not permit insertion of a large diamenter stent and the urethra itself does not retain the stent in the desired position.

The urethra and many other natural cavities (such as the ureters, the biliary tract, the airways, the intestine, the blood vessels) in the human body are compliant in the transverse plane and allows expansion of a stent or parts thereof after the stent has been placed in a desired position. Stents are known which can concentrically expand or which can expand after placement in a desired position in a body cavity. These stents expand equally much in the entire length of the stent. Examples are PCT/SE 2083,00131 which is a selfexpanding stent consisitng of a number of curved and tubularly wowen wires of spring steel as well as a tubularly shaped Titanium stent developed by the American company ASI (Advanced Surgical Intervention Inc.), San Clemente, Californien). The Titanium stent has shifting

plackets which open when the stent is expanded with a luminally placed balloon which forces the stent out to a previously determined diameter. Both these stents become shorter after expansion which is a disadvantage during use because it impedes exact placement of the expanding stent. Additionally both these stents are firmly grown over with tissue after some time requiring special equipment for removal because the stents consist of many wires or a rigid tube.

Furthermore there is a known expanding stent of helically coiled SMA wire, US patent 4.503.569. This stent expands equally much in its entire length and it becomes shorter during the expansion. Aditionally the stent is descibed as made of a variation of SMA with an unfavourable high transition temperature (the temperature required for activation of the shape memory effect).

These types of expanding or expandable stents assumes that the whole of the actual natural cavity take on or will tolerate to be forced to adopt the expanded diameter of all of the stent. This is possible in natural cavities of relatively uniform diameter and continuity. But many natural cavities does not have such uniform diameter and many natural cavities have anatomically conditioned widenings and

orifices. In such natural cavities it is more suitable with a stent which exclusively expands in one or more segments or a stent which expands considerably more in one or more segments of the stent. This is particularly suitable because a segmentary expansion will better fasten the stent in a desired position in a natural cavity and particularly if such position is in or near a change of dimension or an orifice in the natural cavity.

There are known stents with slits which can form basketlike, longitudinal bulges on one ore more segments of the stent. Such a stent made of rubber is known from R.S. Munro og F.B. Scott, the journal "UROLOGY", November 1976, vol.8, no. 5, p. 492-494 and also a stent made of polyurethane from Nissenkorn I, 22nd Congress, Societé Internationale d'Urologie, Nov 1991. Abstract nr. 580. These stents have some important disadvantages among others the above mentioned change of length. Aditionally it is inexpedient that the stents do not expand in all the circumference but only have longitudinal bulgings. In this way the fastening of these stents is poor. It is further inexpedient that the lumen of these stents is the same before and after expansion.

The purpose of the present invention is to eliminate the

majority of the disadvantages with the known stents.

This purpose is achieved in accordance with the invention which is characteristic in that it consists of a single helically coiled wire of SMA where one or more segments of the coil can be brought to expand after the stent has been placed in a desired position in a natural cavity. The construction furthermore allows the possibility of expansion of the total length of the coil but with excessive expansion of one or more segments of the coil. The or those parts of the stent which does not expand or expands considerably less, can possibly be densely coiled whereby scartissue or the like have difficulty in growing into the lumen of the stent (this is known from densely coiled stents of steel wire). The memory effect allows that one or more previously defined segments of the stent can be brought to expand when the stent is placed in a desired position in a natural cavity. The memory effect additionally allows larger expansion of a coil consiting of a single wire than what can be achived with wire of known materials with spring capabilities. A particularly effective fastening of the stent in the desired position is achieved by the relatively large expansion of the stent. The memory effect further means that the wire does not need to be tensed during the insertion whereby the insertion does not require equipment

resistent to torsion.

The invention can chiefly be used in the male urethra and particularly the part of the male urethra passing through the prostate. The stent according to the invention can aditionally be used in other positions in the urethra, in the biliary tract, the blood vessels and the the gatroin testinal tract and also in other natural cavities in the human body.

The following will refer to the drawing which describes a particularly suitable design of the invention. When the drawn stent has been placed in the part of the male urethra which passes through the prostate and expansion has taken place of the segment of the stent closest to the external urethral sphincter, the stent will remain in position and allow urinary passage without obstructing the function of the sphincter. With this particular design the outer diameter of the stent is between 5mm and 8mm before expansion and between 9mm and 13mm after expansion. The thickness of the SMA wire is between .6mm and .9mm. The transition temperature (i.e. the temperature which activates the memory effect) in the utilized SMA is in the interval +38.5°C to +50°C.

In case the stent shall be used in other natural cavities for example the stent length and diameter and the wire thickness can be changed accordingly.

Referring to the drawing, fig. 1 is a preferred design of the stent according to the invention where 1 indicates a helically coiled wire of SMA. 2 indicates a segment of the stent which can be brought to expand by termical treatment in the interval +38.5°C to +50°C. In fig. 2 3 indicates the expanding segment after expansion has taken place. In fig. 3 the stent is seen used in the part of the male urethra passing through the prostate 4. 5 indicates the male urinary sphincter. 6 is the bladder.

PATENT CLAIMS

1. Tubular endoluminal protshesis (a stent) c h a r a c t e r i s e d in consisting of a single helically coiled, or in other ways as a tubular structure shaped, wire of Nickel-Titanium alloy with memory capability and a primary shape where one or more segments has a diameter which is considerably greater than the rest of the stent and a secondary shape where the or those segments with the greater diameter or possibly the total coil has been reduced to the same or a smaller diameter, whereby the release of the memory capability of the material will bring the stent to expand as it returns to the primary shape.

2. Stent according to claim 1, c h a r a c t e r i s e d in that the Nickel-Titanium SMA has a transition temperature between +38,5°C and +50°C.

3. Stent according to claims 1 and 2, c h a r a c t e r i s e d in that the diameter of the wire is between .3mm and 1.0mm.

4. Stent according to claim 1, c h a r a c t e r i s e d in that the stent is equally long before and after expansion.

5. Stent according to claims 1, 2, 3 and 4, c h a r a c-

t e r i s e d in that the coil has an outer diameter of 2mm to 9mm before expansion and up to 4mm to 15mm after expansion.

6. Stent according to claims 1, 4 and 5, c h a r a c t e r i s e d in that an expanding segment is situated in one end of the coil.

7. Stent according to claims 1, 4 and 5, c h a r a c t e r i s e d in that there is an expanding segment in each end of the coil.

8. Stent according to claims 1, 4 and 5, c h a r a c t e r i s e d in that the part of the coil which does not expand or which expands considerably less is densely coiled.

9. Stent according to claims 1 and 2, c h a r a c t e r i s e d in that the Nickel-Titanium SMA becomes soft at a temperature of between +8,5°C and 20°C.

10. Stent according to claim 1, 3, 4, 5, 6 and 8 c h a r a c t e r i s e d by that a smaller number of threads in one end of the stent is not densely coiled.

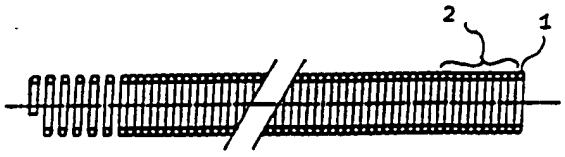


FIG 1

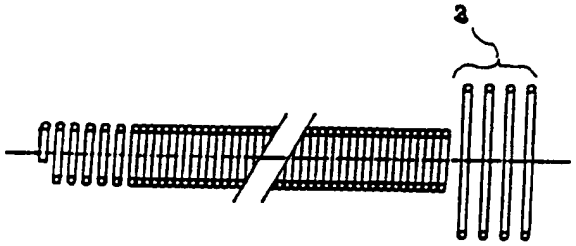


FIG 2

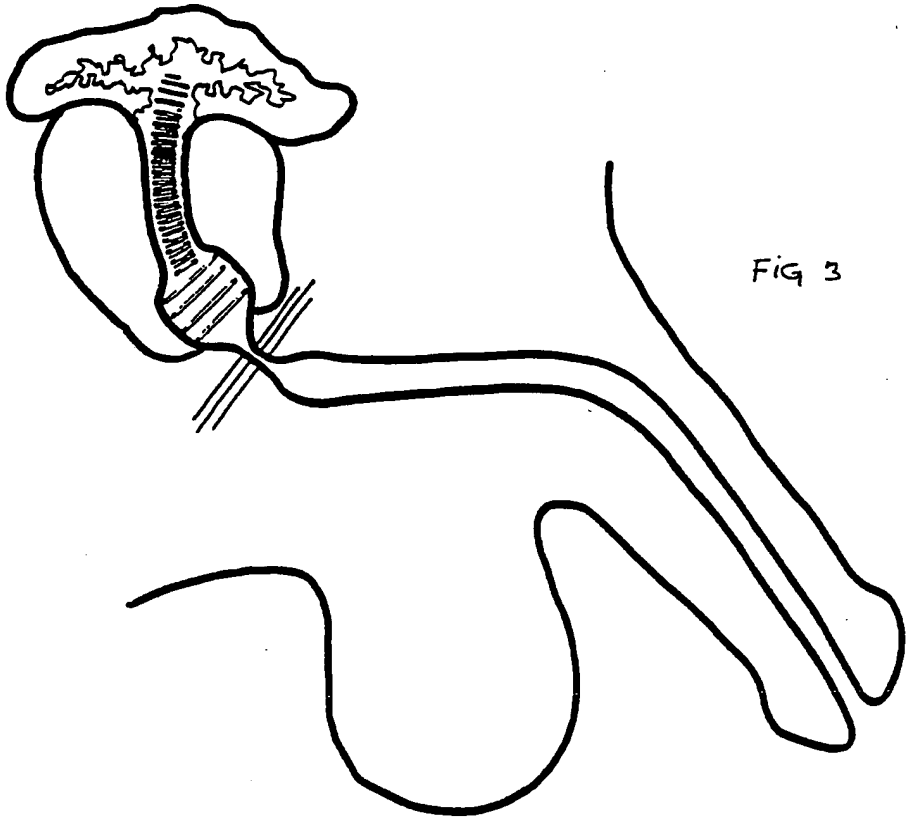


FIG 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 93/00015

A. CLASSIFICATION OF SUBJECT MATTER

IPC5: A61M 29/00 // A61F 2/04, A61M 25/04
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC5: A61F, A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, CLAIMS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4503569 (DOTTER), 12 March 1985 (12.03.85) --	1-2,6-8
Y	US, A, 4950258 (KAWAI ET AL), 21 August 1990 (21.08.90), see e.g. fig 3 and adherent text --	1-2,6-8
Y	US, A, 5025799 (WILSON), 25 June 1991 (25.06.91), memory alloy wire segmentally annealed, see e.g. portions 32,44 and 48 and adherent text --	1-2,6-8
Y	Patent Abstracts of Japan, Vol 13,No 190, C-593, abstract of JP, A, 1-17658 (NIPPON ZEON CO LTD), 20 January 1989 (20.01.89) --	1-2,6-8

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 April 1993	29 -04- 1993
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Leif Vingård Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 93/00015

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP, A1, 0395098 (TERUMO KABUSHIKI KAISHA), 31 October 1990 (31.10.90), selected portion of memory alloy wire heat treated for memory effect	1-2,6-8
A	US, A, 4601283 (CHIKAMA), 22 July 1986 (22.07.86), memory alloy segmentally actuated by segmetally heating	
A,P	DE, C1, 4108269 (OSYPKA), 17 June 1992 (17.06.92)	1,6,7
A,P	US, A, 5143085 (WILSON), 1 Sept 1992 (01.09.92), memory alloy wire segmentally annealed, see e.g. portions 32,44 and 48 and adherent text	1,6-8
A,P	EP, A1, 0481365 (ANGIOMED AG), 22 April 1992 (22.04.92)	1,4,10

INTERNATIONAL SEARCH REPORT

Information on patent family members

31/03/93

International application No.
PCT/DK 93/00015

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4503569	12/03/85	NONE	
US-A- 4950258	21/08/90	EP-A- 0326426	02/08/89
US-A- 5025799	25/06/91	US-A- 5143085	01/09/92
EP-A1- 0395098	31/10/90	AU-B- 623006	30/04/92
		AU-A- 5451590	01/11/90
		JP-C- 1716271	27/11/92
		JP-A- 2289265	29/11/90
		JP-B- 4002273	17/01/92
		US-A- 5069226	03/12/91
		JP-C- 1716272	27/11/92
		JP-A- 2289266	29/11/90
		JP-B- 4002274	17/01/92
		JP-A- 2289267	29/11/90
		JP-B- 4008065	13/02/92
US-A- 4601283	22/07/86	DE-A- 3248389	28/07/83
DE-C1- 4108269	17/06/92	NONE	
US-A- 5143085	01/09/92	US-A- 5025799	25/06/91
EP-A1- 0481365	22/04/92	DE-U- 9014230	21/11/91
		JP-A- 4256759	11/09/92